MAR 2 0 2006

510(k) SUMMARY
ASCLEPION LASER TECHNOLOGIES GmbH
MeDioStar miXT Laser System

K060459

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH QuadroStar 980 Laser System is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

Applicant:	ASCLEPION LASER TECHNOLOGIES GmbH Goeschwitzer Str. 51-52 07745 Jena, Germany
Contact Person:	Mr Reinhard Thieme Quality Assurance and International Regulatory Affairs
Phone: Fax: e-mail:	+49 3641 220 211 +49 3641 220 322 reinhard.thieme@asclepion.com
Preparation Date:	January 31st, 2006
Device Name:	QuadroStar 980
Common Name:	QuadroStar 980
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.481
Equivalent Device:	Ceralas D 980
Device Description:	The QuadroStar 980 is a diode laser system emitting a laser beam at a wavelength of 980 nm with a maximum power of 25 W.
Intended Use:	Delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers or catheters. The QuadroStar 980 is generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery cardiothoracic surgery. This QuadroStar 980 is

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specifically indicated for hemostasis and coagulation of soft tissue (including cardiac tissue).

Comparison to: The QuadroStar 980 Laser System is substantially equivalent to the Ceralas D 980 Laser System, with the same principles of operation, the same wavelength and essentially the same power range as the predicate device for the same indications for uses.

Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The QuadroStar 980 Laser System is another safe and effective device for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers or catheters. The QuadroStar 980 is generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery cardiothoracic surgery. This QuadroStar 980 is specifically indicated for hemostasis and coagulation of soft tissue (including cardiac tissue).

Additional Information : None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Asclepion Laser Technologies GmbH
c/o Mr. Reinhard Thieme
Goeschwitzerstrasse Str. 51-52
07745 Jena, Germany

Re: K060459
Trade/Device Name: QuadroStar 980
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II (two)
Product Code: OCL, GEX
Dated: February 14, 2006
Received: February 22, 2006

Dear Mr. Thieme:

This letter corrects our substantially equivalent letter of March 20, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

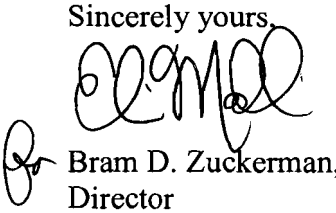
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060459

Device Name: QuadroStar 980 Laser System

Indications for Use:

The QuadroStar 980 Laser System is intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers or catheters. The QuadroStar 980 is generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery cardiothoracic surgery. This QuadroStar 980 is specifically indicated for hemostasis and coagulation of soft tissue (including cardiac tissue).

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K060459

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